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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,854	02/22/2002	Jeno Gyuris	GPCI-P02-106	2615

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BOSTON, MA 02110-2624

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/18/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/080,854

Applicant(s)

GYURIS ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-47 and 55-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's election with traverse of Group V, claims 48-55, species of M13, cp III in Paper No. 10 is acknowledged. The traversal is on the ground(s) that groups V, VI and XI are closely related in nature. Applicants admit that group VI claims are directed to a vector library and cells, Group VI and Group V share common technical features of a vector. Group XI exemplifies the vector recited in group V. But argue that a search covering the subject matter of group V claims necessarily would cover the subject matter of group VI and XI claims. It is further argued that the inventions of groups V, VI and XI can be efficiently searched and examined together without placing a significant additional burden on the examiner and the relevant art for all three groups can be found in the same or related classes. This is not found persuasive because the search is conducted not only under the U.S. Patents classifications. Rather, the search is extended to literature and foreign patents as well. These searches are not co-extensive with the U.S. Patents search. The search of these distinct and different inventions, albeit related, as argued, would impose undue burden on the examiner. The limitation recited in Group V does not necessarily disclose the limitation for a library of Group VI, as argued and claimed.

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The requirement is still deemed proper and is therefore made FINAL.

With respect to the species election, applicants recited MPEP 803.02. The section is argued to state that if the members of the Markush group are sufficiently few in numbers or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In response, because of the differences in the types of phages, a prior art reference anticipating the commonly used M13 would not render obvious  $\phi$ X-174 bacteriophage.

Contrary to applicants' assertion claims 1-66 and 79 do not read on the elected species, since group V is the elected invention. The claims that read on the elected species of group V are claims 48-55. Claims 53 and 55 (in-part) are withdrawn from consideration as directed to non-elected species.

Claims 1-47, 53 and 55 (in-part) and 56-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

### ***Status of Claims***

Claims 1-80 are pending in the application. Claim 80 has been added in the present amendment.

Claims 1-47, 53 and 55 (in-part) and 56-80 (with a random peptide i.e., a library inserted in the vector as shown in the Figures) are withdrawn from consideration, as stated above.

Claims 48-52, 53 (in-part), 54 and 55(in-part) are under examination.

### ***Specification***

The disclosure is objected to because of the following informalities: there is no Seq. ID. Nos. assigned for the peptide sequences recited at page 65, lines 1 and 2. Applicants are requested to check whether these sequences are listed in the Sequence Listing (CRF and paper copy).

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 48, "a population of display packages" is inconsistent or at odds with the preceding statement which does not recite a population of display packages. Also, "in a display mode, the chimeric gene is expressed as a fusion protein..." is not a positive characterization of the product vector. This is more appropriate for a method claim. "Mode" is unclear, within the claimed context, especially in the absence of definition in the specification as to what the term constitutes.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another

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who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 48-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Larocca et al (6,054,312).

Larocca discloses at col. 3, line 30 up to col. 8, line 20 a vector comprising of a chimeric gene comprising a gene that encodes for a test peptide as e.g., FGF ligand fused to a gene that encodes for the surface protein display package as the filamentous phage particles, preferably M13, coat protein gene III or VIII with a RNA splice sites. In the display mode the chimeric protein is display as a fusion protein but in the expression mode in mammalian cells said protein is secreted to the target cells. The vector includes a phage origin of replication and a packaging signal for assembling the vector DNA

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with the capsid proteins. Other elements may be incorporated into the construct. The construct includes a transcription terminator sequence, including a polyadenylation sequence, splice donor and acceptor sites, and an enhancer. Other elements useful for expression and maintenance of the construct in mammalian cells or other eukaryotic cells may also be incorporated (e.g., origin of replication). Because the constructs are conveniently produced in bacterial cells, elements that are necessary or enhance propagation in bacteria are incorporated. Such elements include an origin of replication, selectable marker and the like. Larocca further discloses at col. 3, lines 40-52 that filamentous phage vectors as the M13 are particularly useful vectors in part because they have no native tropism in mammals. Therefore, there is no need to ablate the native tropism of a phage vector to make it useful in gene therapy applications, as is necessary for the more commonly-use retroviral vectors. The phage-based vectors possess numerous other advantages including the ability to accommodate large payloads; the ability to target specific cellular receptors with precision, without injuring healthy cells; and the ability to deliver therapeutic nucleotide sequences to the nucleus of the target cell, thereby enhancing the expression of the therapeutic. Larocca further discloses one



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particularly useful commercial vector, pEGFP-N1, which contains a green fluorescent protein (GFP) gene under control of the CMV immediate-early promoter. This plasmid also includes an SV40 origin of replication to enhance gene expression by allowing replication of the plasmid to high copy number in cells that make SV40 T antigen. Accordingly, the specific vector of Larocca comprising of the specific components fully meets the broadly claimed vector.

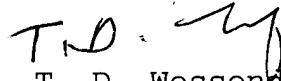
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
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tdw  
April 17, 2003